

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

**P-23277.01 (MTI0908/US)**

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On August 28, 2008

Signature

Typed or printed

Name Mary C. Deutsch**Application Number: 10/713,386****Filed: November 13, 2003****First Named Inventor: William E. Cohn****Art Unit: 3773****Examiner: Erez, Darwin P.**

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☐ attorney or agent of record.

Registration number \_\_\_\_\_

☒ attorney or agent acting under 37 CFR 1.34.Registration number if acting under 37 CFR 1.34 46,346  
SignatureKimberly S. Zillig

Typed or printed name

651-275-9846

Telephone number

August 28, 2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 1 forms are submitted.



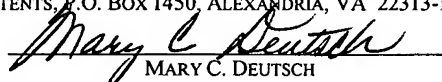
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>Applicant:</b>	<b>William E. Cohn et al.</b>	<b>Examiner:</b>	<b>Erezo, Darwin P.</b>
<b>Serial No.:</b>	<b>10/713,386</b>	<b>Group Art Unit:</b>	<b>3773</b>
<b>Filed:</b>	<b>November 13, 2003</b>		
<b>For:</b>	<b>CARDIAC VALVE PROCEDURE METHODS AND DEVICES</b>	<b>Docket No.</b>	<b>P-23277.01 (MTI0908/US)</b>

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MARY C. DEUTSCH

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Dear Sir or Madam:

This communication is being filed with a Notice of Appeal and a Request for Two-Month Extension of Time Under 37 CFR 1.136(a).

A check in the amount of \$970.00 is enclosed herewith, which includes the fee for the accompanying Notice of Appeal (\$510.00) and for the two-month extension (\$460.00).

It is believed that no other fee is required in filing this submission. However, if any fee is required, please charge the appropriate fee to the Kagan Binder Deposit Account No. 50-1775 and notify us of the same.

**REMARKS**

Each of claims 8, 9 and 11-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,395,014 to Macoviak et al. (hereinafter "Macoviak '014") and in view of U.S. 6,059,757 to Macoviak et al. (hereinafter "Macoviak '757"). It is submitted that each of the present claims 8, 9 and 11-13 are patentably distinct from any attempted combination of Macoviak '014 and Macoviak '757.

The Final Official Action provided that Macoviak '014 disclosed all of the features of independent claim 8 except the feature of a "valve seating retaining ring fixed on the proximal end of the tube; wherein the membrane is tethered to the valve seating retaining ring at multiple spaced apart fixation points around the circumference of the ring." Macoviak '757 was provided to disclose "a valve membrane assembly comprising a valve seating retaining ring (element 20 in Fig. 1, 1(a)-1(b)); a membrane 22 attached to the retaining ring at multiple spaced fixation points around the circumference of the ring; wherein the retaining ring is attached to a catheter via

element 18,” and that it would have been obvious to use such a valve membrane assembly of Macoviak ‘757 in Macoviak ‘014. Further, the Final Official Action provided that the combination of Macoviak ‘014 and Macoviak ‘757 was “still silent with regards to the retainer ring being fixed on the proximal end of the elongated tube,” but that the device in Figure 16 of Macoviak ‘014 included a valve assembly adjacent the open proximal end of the elongated tube, and that it would have been obvious to integrate the valve assembly with the elongated tube.

Applicants filed a Request for Reconsideration After Final in response to the Final Official Action. In response, the Examiner’s Advisory Action provided that the Applicants’ Request did not place the application in condition for allowance. The Examiner referred to Figures 1(a)-1(b) in Macoviak ‘757, and provided that attachment point 20 was a circular ring, and was “viewed as the valve seating retaining ring” having “leaflets (viewed as membranes) tethered thereto.” Also, the Examiner provided that Macoviak ‘014 disclosed that the arrangement taught in Macoviak ‘757 was capable of being used with the filter of Macoviak ‘014, and that it would have been obvious to integrate the two structures.

It is submitted that clear errors exist in the Examiner’s rejection. For one, the Examiner mischaracterized attachment point 20 in Macoviak ‘757 as a valve seating retaining ring, and therefore an element necessary for a *prima facie* case of anticipation was not established. For another, the Examiner failed to show proper motivation for the suggested modifications of Macoviak ‘014 based upon Macoviak ‘757, and therefore a *prima facie* case of obviousness was not established.

Macoviak ‘014 discloses an arterial perfusion catheter with a deployable cerebral embolic protection assembly (CEPA) (Macoviak ‘014: col. 1, lines 22-26). The device in Figure 16 is described as having a CEPA combined with a selectively deployable external flow control valve 644 (Macoviak ‘014: col. 10, lines 43-46). Three U.S. patent applications, one of which being Macoviak ‘757, were incorporated by reference for their descriptions of such a valve (Macoviak ‘014: col. 10, lines 55-60).

Macoviak ‘757 describes a valve 10 (e.g., see Figs. 1 and 2 of Macoviak ‘757) coupled to a catheter 14 at an exterior 16 of the catheter 14. The valve 10 is comprised of leaflets 22 (Macoviak ‘757: col. 7, line 32; col. 8, lines 13-14). Advancement and retraction members 18 couple the leaflets 22 to the catheter 14. The advancement and retraction members 18 are described as being made of material such as “shaped memory metal, stainless steel and the like” (Macoviak ‘757: col. 7, lines 27-30). The members 18 thereby function as leaf springs that bias the leaflets 22 either toward or away from the catheter 14 depending upon the embodiment. The

members 18 put the edge of leaflets 22 into a default operable position. An attachment point 20 is located where an advancement and retraction member 18 and a leaflet 22 are joined together. The attachment point 20 does not seat anything, however.

Figure 1 of Macoviak '757 shows that antegrade flow of blood through the circulatory vessel causes the leaflets 22 to be displaced from catheter 14 and pushed against the wall of the circulatory vessel (leaflets 22 shown in dashed lines) (Macoviak '757: col. 7, lines 64-66). Retrograde blood flow then causes the distal ends of leaflets 22 to move back towards the catheter 14 under the influence of members 18, thereby preventing blood from flowing backwards (Macoviak '757: col. 7, line 67 – col. 8, line 2). In the embodiment in Figure 2, on the other hand, antegrade blood flow causes the leaflets 22 to be displaced toward the catheter 14 (Macoviak '757: col. 7, lines 64-66; col. 8, lines 18-20), and retrograde blood flow causes the leaflets 22 to be pushed against the wall of the circulatory vessel 12 under the influence of members 18, thereby preventing blood from flowing backwards (Macoviak '757: col. 8, lines 21-25, 28-31).

The Examiner erroneously provided that the attachment point 20 is a valve seating retaining ring, as in the present claims. Figures 1 and 2 of Macoviak '757 show that attachment point 20 is just that: a point where an advancement and retraction member 18 is attached to a leaflet 22. Since Figs. 1(a) and 1(b) are cross-sectional views, they show the attachment point 20 along the outer surface of each leaflet 22. There is no description in the specification of attachment member 20 being a ring of any kind, and specifically not a ring that is both attached to an end of a filter tube and that has a membrane connected to its inner surface such that expansion and compression of the membrane expands and compresses the ring and the end of the filter tube, as in the present application. Attachment point 20 is not a ring, and the Examiner's characterization of attachment point 20 as such is a clear error.

Furthermore, the valve seating retaining ring of the present application functions completely differently from the attachment point 20 of Macoviak '757. In the present application, expansion of the membrane causes the valve seating retaining ring to be pushed up against the inner circumference of a vessel wall. The attachment point 20 in Macoviak '757 does not do the same thing. In fact, the specification and figures of Macoviak '757 teach and illustrate that it is the leaflets 22 that are pushed up against the vessel wall during antegrade flow in Figure 1 and during retrograde flow in Figure 2. Thus, there is no valve seating retaining ring disclosed by Macoviak '757. Therefore, together Macoviak '014 and Macoviak '757 do not present all

elements of independent claim 8 and do not render claim 8, nor dependent claims 9, 11-13, unpatentable.

Another clear error exists because the Examiner also failed to show proper motivation for the suggested modifications of Macoviak '014 based upon Macoviak '757. If the valve of Macoviak '757 was used in the device in Macoviak '014, the combination would not result in the presently claimed device. If the Macoviak '757 valve 10 was placed in the CEPA assembly of Macoviak '014, the valve would be connected to the catheter 646 using advancement and retraction members or such equivalents. Such a modification would not result in a valved filter device like that in the present application. The valve portion would not be connected to the filter portion. The valve leaflets would not be tethered to the inner surface of a valve seating retaining ring at discrete points, but would instead be connected to the catheter using advancement and retraction members or equivalents thereof. Thus, expansion of the leaflets would not push against a proximal end of an elongated tube of filter material. Therefore, another clear error exists on the part of the Examiner with regard to the present application.

Additionally, as noted by the Final Official Action, neither reference teaches a retainer ring being fixed on the proximal end of an elongated tube of filter material, as in claim 8. Again, as discussed above, the two references do not disclose, teach or suggest a valve seating retaining ring, therefore such a ring cannot possibly be fixed to the proximal end of the filter tube, as in claim 8. Furthermore, Macoviak '014 provides with regard to the embodiment shown in Figure 16 that the valve and filter are separate and specifically that the valve 644 is mounted on the catheter shaft 646 upstream of the filter 642 (Macoviak '014: col. 10, lines 48-51). Thus, the combination of references does not teach or suggest a way to connect the valve to the filter portion, such as by using a valve seating retaining ring. Furthermore, the two pieces (valve and filter) that are taught by the combination of Macoviak '014 and Macoviak '757 are not the same as the valve and filter portions of the present application. Thus, the valved filter device of the present application is not "an article which has formerly been formed in two pieces and put together," as indicated by the Examiner.

Overall, clear errors were made by the Examiner in the rejection of claims 8, 9 and 11-13. First, the Examiner mischaracterized attachment point 20 in Macoviak '757 as a valve seating retaining ring. Second, the Examiner failed to show proper motivation for the suggested modifications of Macoviak '014 based upon Macoviak '757. Even if the references are combined, they do not teach or suggest connection of a valve portion to a filter portion. In particular, the references do not disclose use of a valve seating retaining ring or equivalent to

join the valve and filter portions. However, even if the combined references were found to disclose such a ring, the leaflets would not be attached to the ring, but instead would be attached to the catheter. Macoviak '014 and Macoviak '757 thereby do not render claim 8, nor its dependent claims 9 and 11-13, unpatentable.


It is, therefore, submitted that presently pending claims 8, 9 and 11-13 are currently in condition for allowance, and a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

### CONCLUSION

It is respectfully submitted that clear errors exist in the rejection of record. For one, the Examiner mischaracterized attachment point 20 in Macoviak '757 as a valve seating retaining ring, and therefore an element necessary for a *prima facie* case of anticipation was not established. For another, the Examiner failed to show proper motivation for the suggested modifications of Macoviak '014 based upon Macoviak '757, and therefore a *prima facie* case of obviousness was not established. A favorable decision by the Conference Panel is appropriate in this case and is hereby requested. In the event that a phone conference between any member of the Conference Panel and the Applicants' undersigned attorney would help resolve any remaining issues in the application, the Examiner is invited to contact the attorney at (651) 275-9846.

Respectfully Submitted,

By:

  
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Dated: August 28, 2008

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